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EDWARDS LIFESCIENCES CORPORATION			VU, QUYNH-NHU HOANG	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/789,181	Applicant(s) MOONEY ET AL.
	Examiner QUYNH-NHU H. VU	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 July 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.
 4a) Of the above claim(s) 6-8,13,14,17,18 and 21-26 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-5,9-12,15,16,19 and 20 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 7/8/09

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Response to Amendment

Amendment filed on 07/08/09 has been entered.

Claims 1-5, 9-12, 1516, 19-20 are present for examination.

Claims 6-8, 13-14, 17-18, 21-26 are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-12, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishijima et al. (US 5,092,846) in view of Brightbill (US 5,149,330).

Regarding claim 1-3, 10-12, Nishijima discloses a multiple lumen access device for medical uses comprising:

an infusion introducer having an access tube 5 with a proximal end and a distal end for introduction into the body, the introducer including a hub 2 connected to the proximal end of the access tube and a hemostasis valve 3 in a fixed location within the hub that provides a seal against blood flow around medical implements that are introduced and withdrawn to and from the body through an access tube lumen, the introducer further including a side arm tube 8 with a side arm lumen communicating with an opening 7 immediately distal the hemostasis valve 3; wherein a medical solution can/(or capable of) flow/flowing through the side arm lumen through the opening 7 and into the access tube lumen to mix with the blood flow immediately distal the hemostasis valve 3;

a catheter including a catheter tube 12 and a junction housing (portion of 9 and 10, Fig. 1B) on a proximal end of the catheter tube, the junction housing having a proximal end and a distal end and including a main channel 10; wherein the main channel 10 being in fluid communication with at least one lumen defined in the catheter tube12;

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and a multi-function adapter 14 having a first unit 16 and a complementary second unit 17 for coupling the catheter to the hub of the infusion introducer such that the catheter tube 12 passes through the hemostasis valve 3 into the access tube lumen, the first unit 16 being attached to the junction housing, and the second unit 16 being fixedly attached to the hub 2, wherein the first unit 16 may be removably connected to the second unit 17.

Nishijima does not disclose at least one auxiliary channel separate from the main channel, the auxiliary channel being in fluid communication with at least one lumen defined in the catheter tube. In other words, the reference of Nishijima is different of the claimed invention such as the junction housing 9 providing multiple extension tube (or multi-auxiliary channel); while Nishijima only provides main channel 10.

Brightbill discloses a similar multiple lumen access device comprising: an introducer 12; a hub connector 35; a catheter tube 14; a junction housing 44; a multi-function adapter 36; wherein the junction housing 44 including a main channel 56; and at least one auxiliary channel 54 or 58 separate from the main channel 56; wherein the main channel 56 and the auxiliary channel 54 or 58 being in fluid communication with at least one lumen defined in the catheter tube 14, see Fig. 2B.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Nishijima with a junction housing having multi-lumen, as taught by Brightbill, in order to delivery different drugs into the catheter tube.

Regarding claims 4, 9, the claimed invention requires that at least one channel on the first unit and a complementary outwardly extending lug on the second unit for engaging the channel. While, the location of first and second unit is opposite with the claimed invention such as: the first unit comprises outwardly extending lugs 16; and the second unit comprises a channel 17. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide opposite location as described in claim 4, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding claim 5, Nishijima in view of Brightbill disclose the claimed invention except for that one of the unit of adapter comprises L-shaped channel. It would have been an obvious matter of design

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choice to provide the channel in different shaped, since it appears that the invention provides the adapter would perform equally well with the adapted of the Nishijima such as the channel in one unit and a complementary outwardly extending lug on the other unit for the same purpose of engaging the channel or two parts together.

Regarding claims 15-16, 19-20, similar to the rejection of claims 1-5 and 11-12 above.

Claims 1-5, 9-12, 15-20 are alternatively rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz et al. (US 5,156,596) in view of Nishijima et al. (US 5,092,846).

Balbierz discloses a multiple lumen access device comprising: an infusion introducer 28 having an access tube with a proximal end and a distal end for introduction into the body; the introducer 28 including a hub 22 connected to the proximal end of the access tube, a valve 70 in a fixed location within the hub that provides a seal around medical implements that are introduced and withdrawn to and from the body through an access tube lumen;

a catheter 28, 52 (Figs. 1-12) including a catheter tube and a junction housing 38 on a proximal end of the catheter tube, the junction housing 38 including a main channel 60 and at least one auxiliary channel 90, 92 separate from the main channel (Fig. 12); the main channel and the auxiliary channel being in fluid communication through the openings 93, 95 (Fig. 12);

a multi-function adapter (including portion of element 24 and element 66) having a first unit and second unit, the first unit being attached to the junction housing 38, and the second unit 24 (proximal portion of hub 22) being fixedly attached to the hub 22 (see Figs. 3-5); wherein the first unit (portion of element 66) maybe removably connected to the second unit.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. the limitation: the first unit may be removably connected to the second unit such that the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it

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from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

Balbierz does not disclose the introducer further including a side arm tube with a side arm lumen communicating with an opening immediately distal with respect to the valve; wherein a medical solution can flow through the side arm lumen through the opening an into the access tube lumen to mix with the blood flow immediately distal the valve.

Nishijima discloses that an introducer including: a infusion introducer 5; a hub connector 2; a valve 3; a side arm 8 with a side arm lumen communicating with an opening 7 immediately distal with respect to the valve; wherein a medical solution can/capable of flow(ing) through the side arm lumen through the opening an into the access tube lumen and able to mix with the blood flow immediately distal the valve.

It has been held that the recitation that a medical solution is "adapted to/capable of/can flow through the side arm lumen through the opening and into the access tube lumen to mix with the blood flow immediately distal the hemostasis valve" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Balbierz with a side arm, as taught by Nishijima, in order to infuse/delivery the drug. Furthermore, the side arm provided and attached into the hub is very well-known in the art for intended use such as infuse/delivery drugs.

Regarding claim 5, Balbierz in view of Nishijima disclose the claimed invention except for the multi-function adapter comprises two L-shaped channels. However, it is well-known in the art to provide L-shaped channels, for example: Figs. 4-7 (different embodiment of Balbierz). Furthermore, it would have been an obvious matter of design choice to L-shaped channels, it appears that the invention would perform equally well with other shaped channels.

Response to Arguments

Applicant's arguments filed 07/08/09 have been fully considered but they are not persuasive.

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1. Applicant argues that Balbierz does not teach a side arm distal of a hemostasis valve. One of ordinary skill in the art would not combine Balbierz and Nishijima.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Balbierz does not disclose the side arm. However, Nishijima fully discloses the side arm structure same as claimed of invention.

2. Applicant argues that Nishijima does not disclose a multi-function adapter for coupling a catheter to an infusion introducer.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a multi-function adapter for coupling a catheter to an infusion introducer) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As noted that, the claim limitation requires "a multi-function adapter for coupling a catheter to the hub of the infusion introducer." It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. a multi-function adapter for coupling a catheter to the hub of the infusion introducer, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974). In this case, Nishijima clearly discloses that a multi-function adapter 14 for coupling a catheter 12 to the hub 2 of an infusion introducer 5.

3. Applicant argues that there is no fluid communication between the lumen of the inner and outer cannula in Balbierz.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a fluid communication between the lumen of the inner and outer cannula) is not recited in the rejected claim(s). Although the claims are

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interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763